



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/525,041	03/14/2000	Daniel R. Soppet	PFI78D2	8342

22195 7590 03/14/2003

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 03/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory ActionApplication No.
09/525,041Applicant(s)
Soppet et alExaminer
UngerArt Unit
1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Dec 13, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Dec 13, 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None

Claim(s) objected to: _____

Claim(s) rejected: 21-24, 26-37, 46-49, 51-63, 72-76, 78-89, 98-115, and 124

Claim(s) withdrawn from consideration: 9-17, 38-45, 64-71, 90-97, and 116-123

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ **SUSAN UNGAR, PH.D**
PRIMARY EXAMINER

10. ☐ Other: _____

Art Unit: 1642

Claim Rejections - 35 USC § 112

1. Claims 21-24, 26-37, 46-49, 51-63, 72-76, 78-89, 98-102, 103-115 and 124 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 16, Section 4, pages 2-6.

Applicant argues that (a) this rejection is contrary to the holding and principles set forth by the United States Supreme Court in In Re Wands since the court does not require that the proteins be well characterized or well known in the art, (b) rejection of the present antibodies claims based on no known function of Colon Specific Protein is inappropriate in view of US Patent No. 6,080,722 to which the present application claims priority and in view of the fact that Applicants have previously explained that the presently claimed antibodies are useful for detecting and targeting colon cancer and Examiner has not presented any countervailing evidence to rebut Applicant's assertions of utility, (c) the colon specific gene is expressed primarily in colon tissues, (d) Examiner has improperly maintained and made final the rejection drawn to inability to determine whether or not the protein encoded by the RNA is overexpressed in colon cancer or that the expressed protein can be used for diagnosis or treatment, despite Applicant's previously reply and reasoning addressing each issue, without providing evidence, reasoning or explanation for doing so, (e) Examiner has disregarded a sworn Declaration wherein objective evidence has been presented, (f) Dr. Bell has predicted overexpression of the protein in human colon cancer, (g) Examiner continues to assert, without any authority or supporting evidence, that mRNA

Art Unit: 1642

expression is not generally predictive of protein expression but has referred to a few exceptions and Examiner has failed to address the arguments and authority cited by Applicant that in most cases, mRNA expression is predictive of protein expression (see Alberts et al as cited in page 5 of the reply submitted July 3, 2002), (h)

Applicant submits references demonstrating that in first-tier characterization of a new gene and protein, investigators most often look to mRNA expression with an understanding that for most genes it is predictive of protein expression to predict tissue specific protein expression levels, (i) Applicant has amended claims 21, 46, 73, 98 to delete references encompassing antibodies which bind “immunogenic fragments”, (j) the claims do not read on proteins that contain “hundreds of other amino acids” since Examiner has not cited a single prior art protein with as few as 30 contiguous amino acids matching SED. ID NO:2, (k) a requirement that claims state the amino acids be exposed on any surface would be inconsistent with settled case law and MPEP guidelines for enablement, (l) the claims are not drawn to a highly variant group of proteins.

The arguments have been considered but have not been found persuasive because (a') the rejection is not contrary to the holding and principles of In Re Wands for the reasons of record. Examiner's response was in direct answer to Applicant's argument that the instant fact pattern is closely analogous to the situation presented in In Re Wands which Examiner clearly demonstrated was not the case. The claimed invention is not enabled for the reasons of record, (b') the instant rejection is not a rejection based on utility but rather is a rejection under enablement, given the information in the specification and the art, no one would

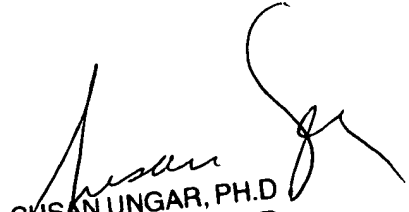
Art Unit: 1642

believe it more likely than not that the presently claimed antibodies are useful for detecting or targeting colon cancer cells for the reasons of record, further, as drawn to US Patent No. 6,080,722, each case is examined on its own merits, (c') for the reasons previously set forth, one cannot determine how to use the claimed invention since it cannot be determined whether the protein to which it binds is differentially expressed in any disease and the protein is expressed in tissues other than colon, (d') Applicant is referred to Paper No. 16, pages 3-4, (e') contrary to Applicant's statement, Examiner has carefully and fully considered Dr. Bell's Declaration, the objective evidence presented is not drawn to expression of the protein in colon cancer tissue compared to normal colon tissue, (f') contrary to Applicant's statement, although Dr. Bell states that it is likely that the protein is overexpressed in colon cancers compared to normal colon tissue, he does not state that the protein will be overexpressed, (g') Applicant is referred to Paper No. 16, page 5, (h') although the references demonstrate that protein can be expressed from mRNA there is no teaching in any of the references that mRNA expression data are most often looked to in order to predict tissue specific protein expression levels nor is there any teaching that mRNA expression data predict tissue specific protein expression levels, (i') the claims still recite comprising "at least 30" and "at least 50" which read on proteins comprising immunogenic fragments, (j') the claim language "comprising" is open language and is not limited to sequences "consisting of". Regardless of the current state of the art, Applicant has not taught how to make the broadly claimed invention, (k') Applicant has not taught how to make the broadly claimed invention, in the absence of such teaching the enablement rejection

Art Unit: 1642

is proper, (1') contrary to Applicant's arguments, as drawn to claims 46 and 98 and those claims dependent upon claims 46 and 98, the proteins recited in the independent claims are highly variable for the reasons set forth previously. rejection.

It is noted that Applicant states that the antibody is required to bind SEQ ID NO:2. Applicant is correct and this ground of rejection is withdrawn.



SUSAN UNGAR, PH.D
PRIMARY EXAMINER